

## MATERIAL SAFETY DATA SHEET

**Product Name: Lidocaine Hydrochloride and Epinephrine Injection**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name And Address**            Hospira Inc.  
 275 North Field Drive  
 Lake Forest, Illinois USA  
 60045

**Emergency Telephone**            CHEMTREC: North America: 800-424-9300;  
 International 1-703-527-3887; Australia (02) 8014 4880

**Hospira, Inc., Non-Emergency**    224-212-2000

**Product Name**                        Lidocaine Hydrochloride and Epinephrine Injection

**Synonyms**                            Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxyilidide, 2-(diethylamino)-, hydrochloride; (-)-3,4-Dihydroxy-a-[(methylamino) methyl] benzyl alcohol

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name**            L-Epinephrine  
 Lidocaine Hydrochloride

**Chemical Formula**                  Lidocaine Hydrochloride - C<sub>14</sub>H<sub>22</sub>N<sub>2</sub>O • HCl  
 Epinephrine - C<sub>9</sub>H<sub>13</sub>NO<sub>3</sub>

**Preparation**                            Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride; sodium hydroxide and/or hydrochloric acid are added to adjust the pH; citric acid and sodium metabisulfite may be added as stabilizer. Multiple-dose vials contain methylparaben 1 mg/mL added as preservative.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
L-Epinephrine	≤ 0.002	51-43-4	DO2625000
Lidocaine Hydrochloride	≤ 2	73-78-9	AN7600000

### 3. HAZARD INFORMATION

**Carcinogen List**

Substance	IARC	NTP	OSHA
L-Epinephrine	Not Listed	Not Listed	Not Listed
Lidocaine Hydrochloride	Not Listed	Not Listed	Not Listed

**Emergency Overview**            Lidocaine hydrochloride and Epinephrine Injection is a solution containing lidocaine hydrochloride, an amide-type local anesthetic used as a local anesthetic for pain management, and epinephrine, a vasoconstrictor agent. In the workplace, this material should be considered possibly irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system and cardiovascular system.

**Occupational Exposure**        Information on the absorption of this product via inhalation or skin contact is not available.

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<b>Potential</b>	Published reports have indicated that similar local anesthetics have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.
<b>Signs and Symptoms</b>	Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal, edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.
<b>Medical Conditions Aggravated by Exposure</b>	Pre-existing hypersensitivity to lidocaine or related amide-type anesthetics. Pre-existing nervous system or cardiovascular ailments.

### 4. FIRST AID MEASURES

<b>Eye contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Skin contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

### 5. FIRE FIGHTING MEASURES

<b>Flammability</b>	None anticipated from this aqueous product.
<b>Fire &amp; Explosion Hazard</b>	None anticipated from this aqueous product.
<b>Extinguishing media</b>	As with any fire, use extinguishing media appropriate for primary cause of fire.
<b>Special Fire Fighting Procedures</b>	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Spill Cleanup and Disposal</b>	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb any liquid with suitable material and
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clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

### 7. HANDLING AND STORAGE

<b>Handling</b>	No special handling required under conditions of normal product use.
<b>Storage</b>	No special storage required for hazard control. For product protection, follow temperature storage recommendations noted on the product case label, the primary container label, or the product insert.
<b>Special Precautions</b>	No special precautions are required for hazard controls.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Exposure Guidelines

Component	Type	Exposure limits			Note
		mg/m <sup>3</sup>	ppm	µg/m <sup>3</sup>	
Lidocaine Hydrochloride	Not Applicable	N/A	N/A	N/A	None Established
L-Epinephrine	Hospira EEL	N/A	N/A	1	8 Hr TWA
L-Epinephrine	Hospira STEL	N/A	N/A	20	STEL

<b>Respiratory protection</b>	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols or vapors is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
<b>Skin protection</b>	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
<b>Eye protection</b>	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
<b>Engineering Controls</b>	Engineering controls are normally not needed during the normal use of this product.

### 9. PHYSICAL/CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	Liquid
<b>Color</b>	Clear, colorless
<b>Odor</b>	Not determined
<b>Odor Threshold:</b>	NA
<b>pH:</b>	2% solution is between 3.3 and 5.5
<b>Melting point/Freezing point:</b>	NA
<b>Initial Boiling Point/Boiling Point Range:</b>	NA
<b>Evaporation Rate:</b>	NA

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<b>Flammability (solid, gas):</b>	NA
<b>Upper/Lower Flammability or Explosive Limits:</b>	NA
<b>Vapor Pressure:</b>	NA
<b>Vapor Density:</b>	NA
<b>Specific Gravity:</b>	NA
<b>Solubility:</b>	Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature:</b>	NA
<b>Decomposition temperature:</b>	NA

### 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined.
<b>Conditions to avoid</b>	Not determined.
<b>Incompatibilities</b>	Strongly alkaline conditions. Methyl vinyl ether; zinc.
<b>Hazardous decomposition products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides and nitrogen oxides (NOx), and hydrogen chloride.
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

### 11. TOXICOLOGICAL INFORMATION

#### Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Lidocaine Hydrochloride	100	LD50	Oral	220 292	mg/kg mg/kg	Mouse
Lidocaine Hydrochloride	100	LD50	Intraperitoneal	122 63	mg/kg mg/kg	Rat Mouse
Lidocaine Hydrochloride	100	LD50	Intravenous	21 15 25.6 24.5	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Rabbit Guinea Pig
Lidocaine Hydrochloride	100	LD50	Intratracheal	28	mg/kg	Rabbit
L-Epinephrine	100	LD50	Intravenous	150 217	mcg/kg mcg/kg	Rat Mouse
L-Epinephrine	100	LD50	Dermal	62	mg/kg	Rat
Epinephrine Hydrochloride	100	LD50	Oral	90	mg/kg	Mouse
Epinephrine Hydrochloride	100	LD50	Intravenous	70	mcg/kg	Rat
Epinephrine Hydrochloride	100	LD50	Intraperitoneal	1.25 7.8	mg/kg mg/kg	Rat Mouse
L-Epinephrine Hydrochloride	100	LD50	Oral	24	mg/kg	Rat

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<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of lidocaine.
<b>Reproductive Effects</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of lidocaine.
<b>Mutagenicity</b>	The mutagenic potential of lidocaine was evaluated in the Ames Salmonella reverse mutation assay, an in vitro chromosome aberrations assay in human lymphocytes and in an in vivo mouse micronucleus assay. There was no indication of any mutagenic effect in these studies.
<b>Carcinogenicity</b>	Long-term studies in animals to evaluate the carcinogenic potential of most local anesthetics, including lidocaine, have not been conducted.
<b>Target Organ Effects</b>	Based on clinical use, possible target organs include the nervous system and the cardiovascular system.

## 12. ECOLOGICAL INFORMATION

<b>Aquatic Toxicity</b>	Not determined for product.
<b>Persistence/Biodegradability</b>	Not determined for product.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal</b>	Epinephrine is listed as a hazardous waste. However, it is not the sole active ingredient in this product. All wastes must be properly characterized by the waste generator. Disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

**14. TRANSPORTATION INFORMATION**

**ADR/ADG/ DOT STATUS:** Not regulated  
**IMDG STATUS:** Not regulated  
**ICAO/IATA STATUS:** Not regulated  
**Transport Comments:** Not Listed

**15. REGULATORY INFORMATION**

**USA Regulations**

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
L-Epinephrine	Listed	Listed	Not Listed	Not Listed	Not Listed
Lidocaine Hydrochloride	Listed	Not Listed	Not Listed	Not Listed	Not Listed

**RCRA Status** Epinephrine - Listed  
**U.S. OSHA Classification** Target Organ Toxin  
 Possible Irritant

**GHS Classification** \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

**Hazard Class** Not Applicable

**Hazard Category** Not Applicable

**Signal Word** Not Applicable

**Symbol** Not Applicable

**Prevention** P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

**Hazard Statement** Not Applicable

**Response:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance L-Epinephrine  
 Lidocaine Hydrochloride

**Classification(s):** Not Applicable

**Symbol:** Not Applicable

**Indication of Danger:** Not Applicable

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**Risk Phrases:** Not Applicable

**Safety Phrases:** S23 - Do not breathe vapor.  
S24/25 - Avoid contact with skin and eyes.  
S37/39 - Wear suitable gloves and eye/face protection.

## 16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS

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